REMARKS

Claims 104, 107, 109-113, 115-117 and 127-134 are pending in the application. Claims 104, 107, 109-113, 115-117 and 127-130 stand rejected under §112, first paragraph, as not being enabled by the written description of the invention. Unspecified claims have also been indicated to be rejected under §112, second paragraph, as being vague and indefinite. Claims 104, 107, 109-113, 115-117 and 127-134 stand rejected as being based on a defective reissue oath. Claims 131-134 stand rejected under §102(b) as being anticipated by applicants' disclosure of the prior art "Glucose Elite" product. For the reasons set forth below, reconsideration of the application is respectfully requested.

For the convenience of the Examiner, reproduced below is claim 104 with the amendments made herein shown in tracked changes. These are the only amendments made in this Response.

> 104. (Currently amended) An electrochemical test strip for conducting testing for the concentration of glucose in a blood sample, comprising:
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> a strip body including an edge surface extending about the perimeter of said strip body, said strip body defining a capillary channel and a vent in fluid communication with the capillary channel, said strip body comprising a sample application port open at a location along the edge surface, the capillary channel having opposed sides extending from the sample application port to at least the vent;
>
> at least working and counter electrodes spaced from each other and positioned within the capillary channel at a location spaced from the edge surface;
>
> a test reagent adjacent at least the working electrode; and
>
> visualization means associated with the capillary channel and including a solid, transparent or translucent, viewing material extending from at least adjacent the sample application port and overlying at least a portion of the capillary channel including said working electrode and at least a portion of said counter electrode,
>
> said strip body having opaque portions which, in combination with said viewing material, define a window effective for providing visual confirmation that a sufficient area of the working and counter electrodes is covered with sample to have a minimum sample amount for said test strip.

1. The Rejections Under §112, first paragraph.

The Office has rejected claims 104, 107, 109-113, 115-117 and 127-130 under §112, first paragraph, as not being enabled by the written description of the invention. According to the Office, the claim limitation "opaque portions" is not taught in the original disclosure. The Office further states that the portion of the specification that applicants cited as supporting the limitation does not contain an "explicit teaching [that] the entire surface (16) is opaque."

As a first response, applicants note that the claims do not require that "the entire surface (16) is opaque". For example, claim 104 in relevant part states:

> said strip body having opaque portions which, in combination with said viewing material, define a window effective for providing visual confirmation that a sufficient area of the working and counter electrodes is covered with sample to have a minimum sample amount for said test strip.

The concept of a window is well understood. For example, according to The American Heritage Dictionary, Second College Edition (1985), a "window" is understood to include "A framework enclosing a pane of glass" or "A pane of glass, clear plastic, or similar material enclosed in such a framework." As is evident in the drawings, e.g., FIG. 1, a window 18 is defined which is surrounded on three sides by the opaque portions 27.

The specification (referring to the issued patent document 5,997,817) states at col. 8, lines 27-31 that an "opaque ink is printed on first surface 16 in pattern 27 such that window 18 remains transparent or translucent." Similarly, it is indicated in the disclosure at col. 8, lines 53-65 that the window is "defined by the absence of printed ink." The "pattern" of the opaque ink is evident in the drawings as providing a border surrounding the "window" 18. For example, the member 16 is shown in FIG.1 as having two distinct portions 18 and 27. Solid lines surround the window 18 on three sides and clearly distinguish that portion from the remaining portion of

member 16. It is this "window" that "remains" as the transparent portion not covered with ink. Further, FIGS. 3h and 3i show that the electrodes 5 and 6 are viewable through the window 18 since they are shown in solid lines in that region, but they are not visible under the remaining portions of member 16, and particularly not under the border immediately surrounding the window 18. Thus, it is again evident that the drawings show that member 16 includes opaque portions which surround and define the window 18 as called for in claim 104.

The amendment to claim 104 adds language referring to the window being effective for providing visual confirmation that a sufficient area of the electrodes was covered with sample. This language is substantially a replacement for text which has been deleted from the preceding paragraph of the claim. Further, the language is clearly supported in the specification. The patent states at col. 8, lines 55-59, for example, that the window has dimensions such that "a substantial fraction of the width (greater than about 75%) of the underlying capillary channel is visible through window 18," and at col. 9, lines 1-4 that "the window being full provides assurance that a sufficient area of the working electrode is covered with sample and that a sufficient part of the counter or reference electrode 6 is also covered." The specification further indicates that the window defined by the absence of printed ink is aligned with opening 11, and:

> "when a sample, such as blood, is introduced into the capillary test chamber, through sample application port 20, it is possible for a user of reasonable visual acuity to determine if the window is entirely full of the sample. ... Visual confirmation of the window being full provides assurance that a sufficient area of the working electrode is covered with sample and that a sufficient part of the counter or reference electrode 6 is also covered. This coverage of the electrodes by the test sample is important to achieving an accurate test in a capillary-fill electrochemical biosensor." Col. 8, line 53 through col. 9, line 7.

By comparison, claim 127 similarly indicates that the strip body includes:

> "opaque portions defining a fill area viewable through the viewing material, the fill area extending from adjacent the sample application port continuously up to

> the working electrode and at least a part of the counter electrode and limited to an area of the capillary channel needed to be filled to conduct an accurate test.

In this claim the limitations relating to the "opaque portions" are: 1) the opaque portions define a fill area viewable through the viewing material; and 2) the fill area extends from adjacent the sample application port continuously up to the working electrode and at least a part of the counter electrode, and defines an area of the capillary channel needed to be filled to conduct an accurate test.

Here too the specification as filed discloses the claimed limitations. The limitation that the opaque portions define "a fill area viewable through the viewing material" can be found at col. 8, lines 27-31, where it is stated that the opaque portions define a window 18. The limitation that "the fill area extends from adjacent the sample application port continuously up to the working electrode and at least a part of the counter electrode, and defines an area of the capillary channel needed to be filled to conduct an accurate test" can be found at col. 8, line 27, through col. 9, line 9. The disclosure at col. 8, line 53, through col. 9, line 7 states that "[the] window ... defined by the absence of printed ink ... is align[ed] with opening 11" and "should be chosen such that a substantial fraction of the width (greater than about 75%) of the underlying capillary channel is visible through window." Moreover:

> "when a sample, such as blood, is introduced into the capillary test chamber, through sample application port 20, it is possible for a user of reasonable visual acuity to determine if the window is entirely full of the sample. ... Visual confirmation of the window being full provides assurance that a sufficient area of the working electrode is covered with sample and that a sufficient part of the counter or reference electrode 6 is also covered. This coverage of the electrodes by the test sample is important to achieving an accurate test in a capillary-fill electrochemical biosensor." Col. 8, line 61 to col. 9, line 6.

The Office suggests that there is no explicit teaching that the entire surface 16 of the disclosure is opaque, and postulates that the pattern 27 could be printed instructions or other

printed matter. There is no support for this contention, and instead it is directly contrary to the specification as already indicated.

In view of the foregoing, reconsideration and withdrawal of the rejections under §112, first paragraph, is respectfully requested.

2. The Rejections Under §112, second paragraph.

The Office has rejected unspecified "claims" under §112, second paragraph, as being vague and indefinite. According to the Office, the claims are indefinite "as to the positioning of the opaque portion with respect to the remainder of the strip (e.g. is the remainder of the strip opaque except for the viewing area?)."

Applicants respectfully submit that claim 104 is not vague and indefinite by reciting a device that includes opaque portions defining a window allowing confirmation of a minimum sample amount for the test strip. That claim language clearly and unambiguously defines the nature and scope of the opaque portions that combine with the viewing material to define a viewing area. Beyond that, the claim does not and need not say anything about whether other portions of the strip may be opaque.

Similarly with respect to claim 127, the claim language is not vague or indefinite by reciting a device that includes opaque portions defining a fill area viewable through the viewing material, the fill area extending from adjacent the sample application port continuously up to the working electrode and at least a part of the counter electrode and limited to an area of the capillary channel needed to be filled to conduct an accurate test. Here too, the claim language clearly and unambiguously defines the nature and scope of the opaque portions that cooperate with the viewing material to define a fill area. Beyond that, the claim does not and need not say anything about whether other portions of the strip may be opaque.

The claims of the present invention should be readily understood in the context of their stated functions. Unlike the prior art, the present invention provide a test strip which includes a viewing area which is positioned such that filling the viewing area is an indication that the test strip has been sufficiently dosed with a blood sample. If the window is too large, or in the wrong location, then it may not totally fill even if there is sufficient sample, or it may totally fill when there is not a sufficient sample. The concept and the function of the window is clear from the specification to a person of ordinary skill in the art. It should be equally clear that it is not necessary to address matters in the claims which are not a part of the invention. If one was building a wall of a house, one might say that a viewing area is desired in a particular location – because there is something important to be seen in that area. That structure and function do not impose any restriction as to what may appear in the wall at other locations. Similarly, applicants need not characterize other aspects of the claim test strips which are not part of the invention, and which would therefore unduly limit the claim scope.

As previously indicated the Office Action did not state which claims were rejected under §112, second paragraph. To the extent other claims are indicated by the rejection, it is believed that the above comments would apply. In view of the foregoing, reconsideration and withdrawal of the rejections under §112, second paragraph, is respectfully requested.

3. The Rejections Based on the Reissue Oath/Declaration.

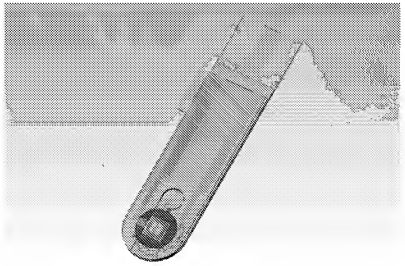
Applicant will submit new Reissue Oaths when patentable subject matter has been indicated.

4. The Rejections Based on §102.

Claims 131-134 stand rejected under §102(b) as being anticipated by applicants' disclosure of "Glucose Elite." According to the Office, claims 131-134 do not have the limitation of an opaque area, and accordingly are anticipated by the "Glucose Elite" device.

Initially, applicants note that claims 132 and 133 do have the "opaque area" limitation since claim 132 depends from claim 104 and claim 133 depends from claim 127. Applicants will therefore treat the §102(b) rejections as applying only to claims 131 and 134.

In applicants' prior remarks it was noted that there is nothing in the "Glucose Elite" product (properly the Glucometer Elite product) which provides opaque and/or colored portions which define a viewing area that indicates an area of the capillary channel which needs to be filled to conduct a test. When blood is dosed to the Glucometer Elite strip, the user is able to see blood enter the strip, but is not able to tell if it is filling the capillary channel or some lesser portion of the interior of the strip. Thus, even to the extent that the Glucometer Elite device includes a colored top layer or colored portions of the top layer, the colored portions do not define a viewing area that indicates an area of the capillary channel which needs to be filled to conduct a test, as can be seen from the Glucometer Elite device shown below.



In contrast to the Glucometer Elite device, applicants' pending claims are directed to a test strip which includes opaque or colored portions specifically located to enable the user to monitor whether sufficient dosing of the test area of the strip has been accomplished. More particularly, the invention provides opaque or colored portions which are positioned adjacent opposite sides of the capillary channel such that only portions of the chamber are viewable in this area. With these opaque/colored areas it is possible for a user of reasonable visual acuity to determine if the window is entirely full of the sample. This makes it possible with applicants' device to provide feedback for the user of the test strip that the strip has been sufficiently dosed with a test sample.

Applicants' specification disclosed that the top layer could be opaque or colored to provide the benefits discussed above. While claims 104 and 127 are directed to devices that use an opaque portion to define the viewing area, claims 132 and 134 relate to devices having "colored portions generally aligned with the opposed sides of the capillary channel" and "the viewing material and the colored portions defining a viewing area required to be filled to have a minimum sample amount for said test strip." As with claims 104 and 127 discussed above, these claim limitations clearly distinguish the present invention from the Glucometer Elite test strip, which fails to provide opaque and/or colored portions which define a viewing area or fill area that confirms sufficient filling of the test strip when that area has been filled with the blood sample.

In view of the above it is submitted that claims 132 and 134 are therefore uniquely distinguished from the above-described prior art. Reconsideration of the application and allowance of the pending claims are therefore respectfully requested.

5. Conclusion.

It should be understood that the above remarks are not intended to provide an exhaustive basis for patentability or concede the basis for the rejections in the Office Action, but are simply provided to overcome the rejections made in the Office Action in the most expedient fashion. In view of the above amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and an early notice of allowance is earnestly solicited.

Respectfully submitted,

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